

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: 11/17/2015

Subject: **Trifloxystrobin:** Evaluation of Proposed Tolerances for Tuberous and Corm Vegetables (Subgroup 1C), Leafy Greens (Subgroup 4A), Leafy Petioles (Subgroup 4B), Head and Stem *Brassica* Vegetables (Subgroup 5A), Leafy *Brassica* Greens (Subgroup 5B), Small Fruit Vine Climbing (Except Fuzzy Kiwifruit) (Subgroup 13-07F), Low Growing Berry (Subgroup 13-07G), Herbs (Subgroup 19A), and Spices (Subgroup 19B).

PC Code: 129112	DP Barcode: D428501
Decision No.: 492388	Registration No.: 264-776, 264-826
Petition No.: 4F8288	Regulatory Action: Section 3 Registration
Risk Assessment Type: NA	Case No.: NA
TXR No.: NA	CAS No.: 141517-21-7
MRID No.: See summary below	40 CFR: §180.555

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MRID Summary Table		
MRID No.	Study Type	Comments
47567023	860.1500 (Magnitude of residue – Leafy vegetables)	47567023.der.doc
47567025	860.1500 (Magnitude of residue – Head and stem brassica)	47567025.der.doc
47567027	860.1500 (Magnitude of residue – Leafy brassica)	47567027.der.doc
47567037	860.1500 (Magnitude of residue – Herbs)	47567037.der.doc
47567101	860.1500 (Magnitude of residue – Spices)	47567101.der.doc
47021101	860.1500 (Magnitude of residue – Strawberries)	47021101.der.doc

NOTE: The DERs were previously reviewed by HED and referenced herein (D363727, Debra Rate, 09/09/2010).

I. Action Requested

The registrant, Bayer CropScience, has submitted a petition (PP#4F8288) proposing new tolerances for residues of trifloxystrobin in or on the following commodities: tuberous and corm vegetables (subgroup 1C), leafy greens (subgroup 4A), leafy petioles (subgroup 4B), head and stem *Brassica* vegetables (subgroup 5A), leafy *Brassica* greens (subgroup 5B), small fruit vine climbing (except fuzzy kiwifruit) (subgroup 13-07F), low growing berry (subgroup 13-07G), herbs (Subgroup 19A), and spices (Subgroup 19B).

Data were previously submitted for all of the above crop subgroups and tolerances were calculated using the NAFTA tolerance calculator (D363727, Debra Rate, 09/09/2010). However, these tolerances were never established and the previously existing tolerances on grape and strawberry were not expanded to cover their respective crop subgroups.

The new petition requests that the previously submitted data be used with the Organization for Economic Cooperation and Development (OECD) statistical spreadsheet to estimate Maximum Residue Limits (MRLs) for the subgroups. The existing grape tolerance will be expanded to cover subgroup 13-07F and the existing strawberry tolerance be increased and then expanded to cover subgroup 13-07G.

II. Conclusion

The residue chemistry database for trifloxystrobin is adequate to support the proposed uses. Adequate metabolism studies, storage stability, crop field trial, and processing data are available. Acceptable methods are available for enforcement of the proposed tolerances.

The residue of concern for tolerance enforcement is the combined residues of trifloxystrobin and its acid metabolite CGA-321113, expressed in parent equivalents.

Based on OECD tolerance calculation procedures, HED concludes that the proposed tolerances listed in Table 1 below are appropriate. A tolerance of 3.5 ppm currently exists for leafy petioles subgroup 4B; this petition is changing the use pattern from a 14-day to a 0-day PHI and the increase in tolerance reflects that change. The current tolerances for grape and strawberry can be expanded to cover residues in their crop subgroups 13-07F and 13-07G, respectively. The tolerance for strawberry was also recalculated based on previously submitted data and increased. The value for the tuberous and corm vegetable subgroup 1C is based on the combined limit of quantitations (LOQs) of the enforcement analytical methods for the analytes of concern, as no residues were detected in any of the field trials. The proposed tolerance for spice subgroup 19B (except black pepper) is not appropriate as black pepper is a representative commodity and cannot be excluded. Therefore, a tolerance on dill seed only is being recommended. A revised section F is requested to correct the commodity definitions for several tolerances.

Table 1. Proposed Tolerance Summary for Trifloxystrobin.			
Commodity	Proposed Tolerance (ppm)	HED Recommended Tolerance (ppm)	Comments <i>Correct Commodity Definition</i>
Leafy greens, subgroup 4A	30	30	Leafy greens subgroup 4A
Leafy petioles, subgroup 4B ¹	9	9	Leafy petioles subgroup 4B
Head and stem brassica subgroup 5A	2	2	<i>Brassica</i> , head and stem, subgroup 5A
Leafy brassica Subgroup 5B	30	30	<i>Brassica</i> , leafy greens, subgroup 5B
Herb, subgroup 19A	200	200	Herb subgroup 19A
Spice, subgroup 19B, except black pepper	30	30	Dill, seed
Tuberous and corm vegetable subgroup 1C	0.04	0.04	Vegetable, tuberous and corm, subgroup 1C
Small fruit vine climbing subgroup (except fuzzy kiwifruit), subgroup 13-07F ²	2.0	2.0	Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F
Low growing berry, subgroup 13-07G ³	1.5	1.5	Berry, low growing, subgroup 13-07G

¹ A tolerance of 3.5ppm currently exists for leafy petioles subgroup 4B. This petition is changing the use pattern from a 14-day PHI to a 0-day PHI.

² The current tolerance on grape (the representative commodity for the subgroup) is being expanded to cover the entire subgroup.

³ The current tolerance on strawberry (the representative commodity for the subgroup) is being expanded to cover the entire subgroup and raised from the existing 1.1 ppm to 1.5 ppm.

Table 2 presents the output from the OECD calculator for the representative crops from each crop subgroup. For each crop subgroup the recommended tolerance is based on the highest output from the calculator for the representative commodities.

Table 2. OECD Calculator Outputs for Trifloxystrobin.	
Commodity	Rounded MRL
<i>Crop Subgroup 4A (leafy green)</i>	
Head lettuce, w wrapper leaves	5
Leaf lettuce, fresh leaves	10
Spinach, fresh greens	30
<i>Crop Subgroup 4B (leafy petioles)</i>	
Celery, stalks with foliage	9
<i>Crop Subgroup 5A (head and stem brassica)</i>	
Broccoli	2
Cauliflower	0.9
Cabbage	1.5
<i>Crop Subgroup 5B (leafy brassica)</i>	
Mustard greens	30

Table 2. OECD Calculator Outputs for Trifloxystrobin.	
Commodity	Rounded MRL
<i>Crop Subgroup 19A (herbs)</i>	
Basil, green leaves	50
Basil, dried leaves	200
Chives	20
<i>Crop Subgroup 19B (spices, except black pepper)</i>	
Dill seed	30
<i>Low growing berry, subgroup 13-07G</i>	
Strawberry	1.5

Note: The representative commodity with the highest residues is bolded and was used for selection of the appropriate tolerance value. It was not necessary to calculate subgroup 13-07F tolerance as this tolerance is being established based on the existing grape tolerance.

Codex MRLs have been established for residues of trifloxystrobin in/on a number of commodities associated with this petition. Codex MRLs are expressed in terms of trifloxystrobin (parent only) while U.S. tolerances are based on the combined residues of trifloxystrobin and its acid metabolite CGA-321113, expressed in parent equivalents. Therefore, harmonization is not possible as the Codex MRLs are likely to be too low based on the U.S. residue definition for tolerance enforcement.

Canadian MRLs are based on the combined residues of trifloxystrobin and its acid metabolite expressed as parent equivalents, and are therefore harmonized with the U.S. enforcement residue definition. The Canadian MRLs are consistent with the established tolerances for potato and grape and, therefore, will be consistent with the proposed U.S. tolerances for the tuberous and corm vegetables subgroup and the small vine climbing fruit, except fuzzy kiwifruit, subgroup. Tolerances will not be harmonized for leafy petioles subgroup 4B as the change in PHI and subsequent increase in tolerance to 9 ppm will no longer be the same as the Canadian MRL of 3.5 ppm. Similarly, the proposed increase in the tolerance for strawberries to 1.5 ppm (and subsequent expansion to subgroup 13-07G) will no longer be harmonized with the Canadian MRL of 1.1 ppm.

Table 3 is a summary of the recommended tolerances and a comparison to Codex MRLs.

Table 3. US Recommended Tolerance/Codex MRL Comparison			
United States		Codex	
US Crop Subgroup	Recommended Tolerance, ppm	Commodity	MRL, ppm
Vegetable, leafy (except <i>Brassica</i>), subgroup 4A	30	Lettuce, Head	15
Vegetable, leaf petioles, subgroup 4B	9	Celery	1
Vegetable, head and stem <i>Brassica</i> subgroup 5A	2	Brussels Sprouts	0.1
		Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	0.5
		Cabbages	0.5
Vegetable, leafy <i>Brassica</i> subgroup 5B	30	None	None
Herb Subgroup 19A	200	None	None

Table 3. US Recommended Tolerance/Codex MRL Comparison			
United States		Codex	
US Crop Subgroup	Recommended Tolerance, ppm	Commodity	MRL, ppm
Spices Subgroup 19B, except black pepper	30	None	None
Tuberous and corm vegetable Subgroup 1C	0.04	Potato	0.2
Small fruit vine climbing subgroup (except fuzzy kiwifruit), subgroup 13-07F	2.0	Grape	3
Low growing berry, subgroup 13-07G	1.5	Strawberry	1

III. References

Recent Memoranda Relevant to Trifloxystrobin			
Author	DP #	Date	Title
D. Rate	363727	09/09/2010	Trifloxystrobin. Application for Section 3 Registration for Use on Globe Artichoke; <i>Brassica</i> Head and Stem and <i>Brassica</i> Leafy Greens, Subgroups 5A and 5B (including Turnip Greens); Grapes and Small Vine Fruits (Except Fuzzy Kiwifruit), Subgroup 13-07F; Herbs and Spices (Except Black Pepper), Subgroups 19A and 19B; Leafy Green Vegetables (Except <i>Brassica</i>), Subgroup 4A; Leaf Petiole Vegetables (Except <i>Brassica</i>), Subgroup 4B; Potato And Other Root, Tuberous, And Corm Vegetables, Subgroup 1C; and Strawberry and Other Low Growing Berries, Subgroup 13-07G. Summary of Analytical Chemistry and Residue Data.
S. Funk	376455	04/14/2010	Trifloxystrobin. Application for Use of an SC Formulation on Grapes, Tomato, Stone Fruit (except Cherry), and Pome Fruit. Grasses Grown for Seed. Summary of Analytical Chemistry and Residue Data: Bridging Studies for SC and WG Formulations. CORRECTION TO D370760 OF MARCH 23, 2010.
S. Funk	370760	03/23/2010	Trifloxystrobin. Application for Use of an SC Formulation on Grapes, Tomato, Stone Fruit (except Cherry), and Pome Fruit. Grasses Grown for Seed. Summary of Analytical Chemistry and Residue Data: Bridging Studies for SC and WG Formulations.
D. Rate	369020, 371443, 371446	08/22/2007	Trifloxystrobin. Section 3 Registration on Asparagus, Vegetable, Root Except Sugar Beet, Subgroup 1B, Radish (Tops), and Papaya, Black Sapote, Canistel, Mamey Sapote, Mango, Sapodilla, Star Apple, Citrus Fruits, Crop Group 10, and Strawberry. Summary of Analytical Chemistry and Residue Data. PP#: 6E7088, 6F7123 and 7F7171.

III. Attachments – OECD Calculator Output

Crop Subgroup 4A (leafy green)

Head lettuce, w wrapper leaves

Residues (mg/kg)	n
0.294	1
0.617	1
1.315	1
1.52	1
2.19	1
2.5	1

Trifloxystrobin
Head lettuce, w wrapper leaves
USA
0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	6
Percentage of censored data	0%
Number of non-censored data	6
Lowest residue	0.294
Highest residue	2.500
Median residue	1.418
Mean	1.406
Standard deviation (SD)	0.859
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	2.500
- Mean + 4 SD	4.843
- CF x 3 Mean	4.218
Unrounded MRL	<u>4.843</u>

Rounded MRL	<u>5</u>
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High uncertainty of MRL estimate.
[Small dataset]

Leaf lettuce, fresh leaves

Residues (mg/kg)	n
0.658	1
3.17	1
3.195	1
3.47	1
3.585	1
4.13	1

Trifloxystrobin
Leaf lettuce, fresh leaves

USA

0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	6
Percentage of censored data	0%
Number of non-censored data	6
Lowest residue	0.658
Highest residue	4.130
Median residue	3.333
Mean	3.035
Standard deviation (SD)	1.215
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	4.130
- Mean + 4 SD	7.896
- CF x 3 Mean	9.104
Unrounded MRL	<u>9.104</u>

Rounded MRL	<u>10</u>
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High uncertainty of MRL estimate.
[Small dataset]

Spinach, fresh greens

Residues (mg/kg)	n
4.82	1
5.37	1
7.605	2
9.56	1
10.45	1

Trifloxystrobin Spinach, fresh greens

USA

0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	6
Percentage of censored data	0%
Number of non-censored data	6
Lowest residue	4.820
Highest residue	10.450
Median residue	7.605
Mean	7.568
Standard deviation (SD)	2.221
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	10.450
- Mean + 4 SD	16.451
- CF x 3 Mean	22.705
Unrounded MRL	<u>22.705</u>

Rounded MRL 30

High uncertainty of MRL estimate.
[Small dataset]

Crop Subgroup 4B (leafy petioles)

Celery, stalks w foliage

Residues (mg/kg)	n
< 0.02	1
0.64815	1
1.0005	1
1.165	1
1.9225	1
5.225	1

Trifloxystrobin
Celery, stalks w foliage

USA

0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	6
Percentage of censored data	17%
Number of non-censored data	5
Lowest residue	0.020
Highest residue	5.225
Median residue	1.083
Mean	1.664
Standard deviation (SD)	1.853
Correction factor for censoring (CF)	0.889

Proposed MRL estimate

- Highest residue	5.225
- Mean + 4 SD	9.076
- CF x 3 Mean	4.436
Unrounded MRL	<u>9.076</u>

Rounded MRL	<u>9</u>
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High uncertainty of MRL estimate.
[Small dataset]

Crop Subgroup 5A (head and stem brassica)

Broccoli

Residues (mg/kg)	n
0.46	1
0.6755	1
0.7	1

Trifloxystrobin

Broccoli

USA

0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	0.460
Highest residue	0.700
Median residue	0.676
Mean	0.612
Standard deviation (SD)	0.132
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.700
- Mean + 4 SD	1.140
- CF x 3 Mean	1.836
Unrounded MRL	<u>1.836</u>

Rounded MRL 2

High uncertainty of MRL estimate.
[Small dataset]

Cauliflower

Residues (mg/kg)	n
0.02	1
0.02315	1
0.3555	1

Trifloxystrobin Cauliflower

USA
0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	0.020
Highest residue	0.356
Median residue	0.023
Mean	0.133
Standard deviation (SD)	0.193
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.356
- Mean + 4 SD	0.904
- CF x 3 Mean	0.399
Unrounded MRL	<u>0.904</u>

Rounded MRL 0.9

High uncertainty of MRL estimate.
[Small dataset]

Cabbage

Residues (mg/kg)	n
0.03795	1
0.1244	1
0.395	1
0.481	1
0.485	1
0.5975	1

Trifloxystrobin

Cabbage

USA

0.246-0.260 lb ai/A; 0-day PHI

Total number of data (n)	6
Percentage of censored data	0%
Number of non-censored data	6
Lowest residue	0.038
Highest residue	0.598
Median residue	0.438
Mean	0.353
Standard deviation (SD)	0.222
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.598
- Mean + 4 SD	1.242
- CF x 3 Mean	1.060
Unrounded MRL	<u>1.242</u>

Rounded MRL	<u>1.5</u>
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High uncertainty of MRL estimate.
[Small dataset]

Crop Subgroup 5B (leafy brassica)

Mustard greens

Residues (mg/kg)	n
5.355	1
6.22	1
7.35	1
7.425	1
7.64	1
8.22	1
8.34	1
9.665	1

Trifloxystrobin
Mustard greens
USA
0.122-1.129 lb ai/A

Total number of data (n)	8
Percentage of censored data	0%
Number of non-censored data	8
Lowest residue	5.355
Highest residue	9.665
Median residue	7.533
Mean	7.527
Standard deviation (SD)	1.320
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	9.665
- Mean + 4 SD	12.806
- CF x 3 Mean	22.581
Unrounded MRL	<u>22.581</u>
 Rounded MRL	 <u>30</u>

Crop Subgroup 19A (herbs)

Basil, green leaves

Residues (mg/kg)	n
12.2	1
13.7	1
21.7	1

Trifloxystrobin

Basil, green leaves

USA

0.122-1.134 lb ai/A

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	12.200
Highest residue	21.700
Median residue	13.700
Mean	15.867
Standard deviation (SD)	5.107
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	21.700
- Mean + 4 SD	36.295
- CF x 3 Mean	47.600
Unrounded MRL	<u>47.600</u>

Rounded MRL 50

High uncertainty of MRL estimate.
[Small dataset]

Basil, dried leaves

Residues (mg/kg)	n
51.35	1
54.55	1
84.8	1

Trifloxystrobin
Basil, dried leaves
USA
0.122 - 1.134 lb ai/A

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	51.350
Highest residue	84.800
Median residue	54.550
Mean	63.567
Standard deviation (SD)	18.458
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	84.800
- Mean + 4 SD	137.399
- CF x 3 Mean	190.700
Unrounded MRL	<u>190.700</u>

Rounded MRL	<u>200</u>
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High uncertainty of MRL estimate.
[Small dataset]

Chives

Residues (mg/kg)	n
4.1	1
4.175	1
10.17	1

Trifloxystrobin
Chives
USA
0.122-1.134 lb ai/A

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	4.100
Highest residue	10.170
Median residue	4.175
Mean	6.148
Standard deviation (SD)	3.483
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	10.170
- Mean + 4 SD	20.081
- CF x 3 Mean	18.445
Unrounded MRL	<u>20.081</u>

Rounded MRL	<u>20</u>
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High uncertainty of MRL estimate.
[Small dataset]

Crop Subgroup 19B (spices, except black pepper)

Dill seed

Residues (mg/kg)	n
1.5	1
7.22	1
12.9	1

Trifloxystrobin
Dill seed
USA
0.122-1.129 lb ai/A

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	1.500
Highest residue	12.900
Median residue	7.220
Mean	7.207
Standard deviation (SD)	5.700
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	12.900
- Mean + 4 SD	30.007
- CF x 3 Mean	21.620
Unrounded MRL	<u>30.007</u>

Rounded MRL	<u>30</u>
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High uncertainty of MRL estimate.
[Small dataset]

Crop Subgroup 13-07G (Low growing berry, subgroup)

Strawberry

Residues (mg/kg)	n
0.1185	1
0.23705	1
0.26905	1
0.30425	1
0.35315	1
0.46845	1
0.5141	1
0.5626	1

Trifloxystrobin

Strawberry

USA

0.598-0.606 (lb ai/A), 0-day PHI

Total number of data (n)	8
Percentage of censored data	0%
Number of non-censored data	8
Lowest residue	0.119
Highest residue	0.563
Median residue	0.329
Mean	0.353
Standard deviation (SD)	0.152
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.563
- Mean + 4 SD	0.960
- CF x 3 Mean	1.060
Unrounded MRL	<u>1.060</u>
Rounded MRL	<u>1.5</u>